

**REMARKS**

**I. Status of the Claims**

Claims 1-12 stand rejected by the Office.

**II. Information Disclosure Statement**

The Office considered the Information Disclosure Statement resubmitted with the Request for Continued Examination, but crossed out two references, asserting that they were not received. Office Action, page 2. The Office also asserts that the Information Disclosure Statement filed May 19, 2005, fails to comply with 37 C.F.R. § 1.98(a)(3) because it does not include a concise explanation of the relevance of each patent listed that is not in the English language. *Id.*

According to the Image File Wrapper, the U.S. Patent and Trademark Office received the references lined thru on May 19, 2005. DE19532396 appears in the Image File Wrapper under the listing "5/19/2005 Foreign Reference" and is a 23 page document. Rapp et al. appears in the Image File Wrapper under the listing "5/19/2005 NPL Document" and is a 60 page document with the serial number 09/030,295 handwritten at the top. Further, both the information Disclosure Statement filed March 21, 2002, and the Information Disclosure Statement resubmitted on May 19, 2005, were in compliance with 37 C.F.R. § 1.98(a)(3) because in each case the Information Disclosure Statement indicated in its text that the relevance of the cited non-English language documents was set forth in the copies of the corresponding U.S. applications and International Search Report included as part of the Information Disclosure

Statement. Applicants respectfully ask that the Office consider the references and provide an initialed PTO/SB/08 indicating that they were considered.

### **III. Rejection of Claims 1-12 under 35 U.S.C. § 112, ¶1**

The Office rejected claims 1-12 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. Office Action, page 2. The entire substance of the Office's rejection is the assertion that "Applicant does not clearly teach what is encompassed by 'improved stability in storage.'" *Id.* at 3.

According to the M.P.E.P., "the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention." M.P.E.P. § 2164.04 (citing *In re Wright*, 999 F.2d 1557, 1562, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993)). Here the Office fails to address any of the factors set forth in *In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988), and discussed in M.P.E.P. § 2164.01(a). These factors must be evaluated before the Office can meet its initial burden.

The claims are drawn to hard caramels with improved stability in storage containing 1,1-GPM and sorbitol within recited ranges. Applicants respectfully note that the specification discloses that reduced water uptake, reduced recrystallization, and reduced discoloration are each indicia of improved stability in storage. *See, e.g.*, Specification, page 3. The working examples provide methods for assessing each of those parameters. *See, e.g.*, Specification, pages 9-13. Thus the specification provides sufficient guidance so that one skilled in the art could determine whether a hard caramel had improved stability in storage without undue experimentation. The level of skill in the

art of hard caramels is high, and the Office provides no evidence that this is an unpredictable art.

The Office has failed to establish a reasonable basis to question the enablement of claims 1-12. Accordingly, Applicants respectfully request the Office to withdraw this rejection.

#### **IV. Rejection of Claims 1-12 under 35 U.S.C. § 103(a)**

Claims 1-12 stand under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,578,339 to Kunz et al. ("*Kunz*") and U.S. Patent No. 6,248,386 to Willibald-Ettle et al. ("*Willibald-Ettle*"). Office Action, page 3. The reasons are the same as set forth in earlier Office Actions with respect to claims 1-8. *Id.* at 3-4. The Office continues to assert that "in the absence of a showing to the contrary, the amount employed are no matter that a matter of choice and well-within the skill of the art and at most are deemed optimization." *Id.* at 3.

The claims of *Kunz* relied upon by the Examiner recite a sweetener (e.g., claim 5) comprising 45% to 60% by weight of 1,1-GPM, or a candy comprising that sweetener (e.g., claim 21). Claim 8 of *Kunz* further indicates that the sweetener contains small amounts of sorbitol. The Office notes that *Willibald-Ettle* teaches hard caramels comprising 1,1-GPM and sorbitol. The Office states that although "the claims differ [from the teachings of the combination of the references] as to the specific amounts employed," the amounts employed are "deemed optimization" so that it would have been obvious "to use the claimed percentages in either Kunz et al or Willibald-Ettle et al

because the use and manipulation of both 1,1-GPM and sorbitol are conventional in the production of hard candies such as caramels." Office Action, pages 3 to 4.

The claimed invention, however, is for a particular type of candy, a hard caramel, containing not only a specific range of 1,1-GPM, but also 0.5% to 3.5% sorbitol by weight. Both *Willibald-Ettle* and *Kunz* mention that sorbitol can be present in sweeteners used to make candy. *Willibald-Ettle* does not teach any particular weight percentage of either 1,1-GPM or sorbitol, however. In addition, while claims 6 and 8 of *Kunz* recite that small amounts of sorbitol can be present in the sweetener, as previously noted and as discussed below, *Kunz* also teaches that *it is desirable to remove the sorbitol*. *Kunz*, col. 3, line 62 to col. 4, line 3 (emphasis added).

In order to properly reject a claim as obvious in view of a combination of prior art references, the Office has the burden of establishing a *prima facie* case that:

(1) . . . the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) . . . the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure.

*In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991) (citations omitted). Here, the Office has failed to satisfy its burden of establishing that claims 1-12 are *prima facie* obvious over the prior art.

The Office has not satisfied its burden because it has not made a clear and particular showing that the references provide the motivation needed to make a hard caramel having the properties claimed. *Kunz* not only teaches that it is desirable to remove the sorbitol, but the Examples of *Kunz* also teach the ordinary artisan how to

accomplish removing the sorbitol from sweeteners by using chromatography (e.g., Example 3 at columns 6 to 7, and Example 7 at columns 8 to 9). In addition, *Kunz* notes that the sweetener of Example 3, which lacks sorbitol, is an “excellent sweetener” (column 7 at lines 20-22), and it is this sweetener lacking sorbitol that is used in Examples 9 and 10 to sweeten food. Further, *Kunz* teaches at column 1, lines 49-52, that mixtures of 1,6-GPS or 1,6-GPM with other sugar alcohols or sugars in the presence of sorbitol yields unsatisfactory products that are sticky. *Kunz*, when taken for all that it teaches, would not have motivated the ordinary artisan to select the particular claimed range of sorbitol for inclusion in a candy. Instead, *Kunz* provides chromatographic approaches for eliminating all sorbitol from a sweetener. Applicants respectfully maintain that *Kunz* motivates the ordinary artisan *to remove as much sorbitol as possible*, thus teaching away from the claimed invention.

Applicants further note that *Kunz* does not teach hard caramels and *Willibald-Ettle* does not teach specific ranges of 1,1-GPM and sorbitol. The Office’s rejection therefore is evidently based on the premise that it would have been obvious to substitute a sweetener as taught by *Kunz* for the sweetener taught by *Willibald-Ettle* in its process of making hard caramels. But because *Kunz* teaches that it is desirable to eliminate sorbitol from the sweetener, the ordinary artisan would not have been motivated by *Kunz* to substitute a sweetener that contains sorbitol in the method of making hard caramels taught by *Willibald-Ettle*. Neither does *Willibald-Ettle* provide any motivation to specifically select the recited ranges of 1,1-GPM and sorbitol based on its disclosure of a process for making hard caramels. There is no motivation for the ordinary artisan to make Applicants’ invention based upon the teachings of the

references. The Office has, therefore, failed to establish a *prima facie* case for rejecting the claims as unpatentable.

Applicants again point out that it is only after the Office has established a *prima facie* case that Applicants have any obligation to provide evidence of nonobviousness, such as unexpected results. See M.P.E.P. § 2142. Because the Office for the reasons discussed has failed to establish a *prima facie* case, Applicant is not, contrary to the Office's assertion, obligated to provide evidence of nonobviousness. Nevertheless, Applicants note that the Specification itself provides evidence of unexpected results, as discussed below. In addition, Applicants include as part of this response a Rule 1.132 Declaration providing yet further evidence that hard caramels containing 1,1-GPM and sorbitol in the recited ranges have unexpectedly superior properties that result in improved stability in storage.

As previously noted, neither *Kunz* nor *Willibald-Ettle*, relied upon by the Office in its obviousness rejection, teach that the stability of a hard caramel can be improved by selecting particular percentages of 1,1-GPM and sorbitol. *Kunz* instead teaches that it is desirable to eliminate the sorbitol, and teaches how to accomplish its removal. See, e.g., *Kunz*, Example 3 at columns 6 to 7, and Example 7 at columns 8 to 9. Further, *Kunz* teaches at column 1, lines 49-52, that mixtures of 1,6-GPS or 1,6-GPM with other sugar alcohols or sugars in the presence of sorbitol yields unsatisfactory products that are sticky. *Willibald-Ettle* also does not teach the selection of specific ranges of 1,1-GPM and sorbitol. Instead, *Willibald-Ettle* is limited to providing a new process for producing a hard caramel. See, e.g., *Willibald-Ettle*, column 1, lines 1-2 and 38-44.

In contrast, the Specification discloses that it is possible to improve the stability of a hard caramel by selecting a particular range of 1,1-GPM concentrations in combination with a particular range of sorbitol concentrations. See Specification at page 2, first and second full paragraphs. As summarized in the first paragraph on page 3 of the Specification, this improved stability in storage, due to the especially low water uptake and lower tendency towards recrystallization of the claimed hard caramels compared to known hard caramels, was surprising. Certainly nothing in *Kunz* suggests that there would be a particular combination of 1,1-GPM and sorbitol concentrations that would lead to this effect, because otherwise *Kunz* would not have taught, as noted *supra*, that it was desirable to eliminate the sorbitol. Likewise, nothing in *Willibald-Ettle* provides such a suggestion.

The Specification provides further evidence that the improved stability observed using concentrations of 1,1-GPM and sorbitol with the claimed ranges was unexpected. First, the experiments summarized in the Figures show that the unwanted water intake and color change of the hard caramels depends upon both the amount of 1,1-GPM and the amount of sorbitol in the hard caramels. Second, the Specification also shows that this effect is not observed when the 1,1-GPM content is less than or greater than the limited range defined by the claims. For example, the Specification on page 11, third paragraph, notes that hard caramels containing only 50 to 51 wt% 1,1-GPM, a concentration below that recited in the claims, rapidly recrystallize, even though they contain 1.4 to 3.5 wt% sorbitol. Hard caramels containing a 1,1-GPM content of more than 60 wt%, the upper limit recited in the claims, have a tendency to crystallize on cooling. Specification, sentence bridging pages 12-13. Further, the Specification

discloses that when the concentration of 1,1-GPM is controlled, hard caramels that include sorbitol have a lower tendency towards recrystallization. Specification, page 12, last paragraph.

The Specification, therefore, demonstrates that hard caramels containing concentrations of 1,1-GPM and sorbitol outside of the recited ranges do not result in properties that impart improved stability to the hard caramel. It is only after Applicants' surprising finding that the ordinary artisan could then appreciate the importance and desirability of the recited concentration ranges. Applicants respectfully submit that, even had the Office established a *prima facie* case of obviousness (for the reasons of record, the Office has not met this burden), the unexpected results described in the Specification provide sufficient evidence of nonobviousness.

Further, the Rule 1.132 Declaration of Dr. Joerg Kowalczyk that accompanies this response shows that hard caramels containing the recited 1,1-GPM and sorbitol amounts are superior in yet another parameter that reflect an improved stability in storage. As both the Declaration and the Specification (e.g., page 2, lines 4-10) show, improved stability in storage has practical significance because it influences the marketability of the hard caramels. Therefore, Applicants respectfully submit that the hard caramels of the invention are unexpectedly superior in yet another property when compared to hard caramels made using concentrations of 1,1-GPM or sorbitol outside the claimed ranges.

Applicants respectfully submit the Office has failed to establish a *prima facie* case of obviousness. Further, the Specification and the evidence provided in the Rule 1.132 Declaration provide ample evidence of unexpected advantageous properties of



the claimed hard caramels to rebut a *prima facie* case had the Office established one.

Accordingly, Applicants respectfully request the Office to withdraw the rejection.

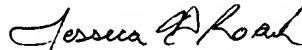
**Conclusion**

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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